**Welcome and Opening Plenary Descriptions**

**Friday, September 30, 2016**

**Time: 8:30 to 9:15**

**Track: Opening Plenary**

**Welcome and Introduction**

The speakers will describe issues related to the practice of clinical research in the current regulatory environment and how SOCRA works to promote education and training within the clinical research community.

*Presenter: Cheryl Chanaud, PhD, CCRP, Vice President, Research, Memorial Hermann Health System*

*Presenter: Susanna Sellmann, BSc, CCRP, MRT, Manager Quality Assurance, Cancer Clinical Research Unit, Princess Margaret University Health Network*

**Time: 9:15 to 10:00**

**Track: Opening Plenary**

**Informed Consent**

Dr. Grady will discuss NIH Clinical Center perspectives on the informed consent process.

*Presenter: Christine Grady, PhD, BSN, RN, FAAN, Chief, Department of Bioethics, National Institutes of Health*

**Time: 10:30 to 11:15**

**Track: Opening Plenary**

The Problem is Big Enough, The Problem is Small Enough: Pediatric Cancer - Current and Future Research

Pediatric oncology clinical trials have the opportunity to lead within the world of cancer research. However, children are often not given the opportunity to be involved in research due to a variety of reasons. Changes are needed in the way that we look at childhood cancer research while continuing to maintain levels of safety and efficacy. Ms. Palmer will discuss the current challenges facing pediatric cancer researchers in Canada and the USA today.

*Presenter: Antonia Palmer, MASC, Co-Founder, Ac2orn: Advocacy for Canadian Childhood Oncology*

**Time: 11:15 to 12:00**

**Track: Opening Plenary**

**ICH E6 GCP Update and Impact**

Ms. Smart will discuss new guidance requirements to ICH GCP. She will describe the impact that the proposed changes will have on practice and discuss some initiatives to prepare for change and implementation.

*Presenter: Jean Smart, RAC, Regulatory Affairs/Quality Management Lead, BC Clinical Research Infrastructure Network*

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**Thank you!**

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**We’d Like to Give Special Thanks to the 2016 Annual Conference Program Committee**

| Harvey Arbit, PharmD, MBA, CCRP, RAC | Donna Headlee, RN, BSN, CCRP |
| Patrica Beers Block, BS, CCRP | John Kessler, PharmD |
| Lisa Benson, BS, CCRP, CRCP | Tammy Neseth, BS, CCRP |
| Cheryl Chanaud, PhD, CCRP | Susanna Sellmann, BSc, CCRP, MRT |
| Helen Darwin, BSc, CCRP | Radhika Sivaramakrishna, PhD, PMP, CSSBB, CCRP |
| Susan Devine, CCRP | Ann Von Worley, BSHS, RN, CCRP |
| Kathi Durdon, MA, CCRP | Nancy Wintering, BA, MSW, LCSW, CRC, CCRP |
| Jennifer Goldfarb, BSN, RN, CCRP | |
| Anatoly Gorkun, MD, PhD, CIPD |  |
### TRACK 1
**Finance & Billing**

**Location:** 524  
**Moderator:** Jennifer Goldfarb

#### Time: 1:15 to 2:00  
**Track:** Finance & Billing

### Evaluating Your Protocol - Can We Really do This Study?

Protocol evaluation is essential to determining the feasibility of a study. Ms. Hapanowicz and Ms. Gaa will discuss the key elements for evaluating protocols. This presentation will discuss financial feasibility according to your institutional policies, potential barriers for recruitment, staffing needs, potential issues and logistical implications, and evaluating staffing and institutional capabilities (departmental access and support).

**Presenter:** Monika Gaa, MBA, CCRP, Senior Feasibility Coordinator, The Research Institute at Nationwide Children’s Hospital  
**Presenter:** Christine Hapanowicz, BA, CCRP, Senior Research Regulatory Coordinator, The Research Institute at Nationwide Children’s Hospital

#### Time: 2:05 to 2:50  
**Track:** Finance and Billing

### Accurately Budgeting for Clinical Research Staff Time

Do you always feel like you never get it right when it comes to budgeting for staff time? Clinical research is complex and dynamic, making study staff time an elusive topic. Our economic climate will no longer allow for efficiencies and under-budgeting so we must learn techniques to budget and plan for appropriate staffing.

**Presenter:** Jennifer Goldfarb, BSN, CCRP, RN, Senior Director, Clinical Research Support Office, Children’s Hospital of Philadelphia

#### Time: 3:25 to 4:10  
**Track:** Finance and Billing

### RE-Tool: Research Efficiency Tool

UTHealth launched an initiative to improve communication and clinical coordinator satisfaction related to clinical research billing. This talk will address the process of engaging research staff and listening to their concerns. We gathered information from the end users to develop RE-Tool in REDCap to improve their processes. The end result is a product that coordinators want to use versus a mandated complicated system.

**Presenter:** Heather Cody, MHA, BBA, Assistant Director, Clinical Research Finance, University of Texas Health Science Ctr at Houston

#### Time: 4:15 to 5:00  
**Track:** Finance and Billing

### Medicare Coverage Analysis - the Foundation of Clinical Research Billing

This session will focus on the development of the Medicare Coverage Analysis and its impact on the clinical research billing / patient billing processes. Participants will learn the federal and applicable state regulations impacting the development of the coverage analysis. Ms. Veazie will also inform the participant on best practices and tips on building a compliant program.

**Presenter:** Mary Veazie, MBA, CPA, CHC, CHRC, Executive Director, Clinical Research Finance, UT MD Anderson Cancer Center

### TRACK 2
**Device Research**

**Location:** 520 c/f  
**Moderator:** Kathi Durdon

#### Time: 1:15 to 2:00  
**Track:** Device Research

### First Breath to Death Sensing Analytics: Pathology Informatics in Precision Medicine

Each of us generates billions of bits of data capture over a lifetime. Making sense of this data to predict and prevent disease, personalize our health care and engage us to participate in the management in our own care will be our future. Dr. Corona will discuss building a learning health system using advanced data analytics that extract patterns from EMRs, gene sequencers, laboratory systems, imaging systems, social media, mobile health and e-health systems, and the future of precision medicine.

**Presenter:** Robert Corona, DO, MBA, FCAP, FASCP, John B Henry Prof/Chair of Pathology & Lab Medicine, SUNY Upstate Medical University

#### Time: 2:05 to 2:50  
**Track:** Device Research

### The State of Innovation in the Canadian Medical Device Industry

Using original research and personal experience leading Canada’s largest medical device design, development, and manufacturing service provider, Mr. Phillips will provide an overview and analysis of the Canadian medical device industry. The presentation will discuss industry size and background, MedTech exits and return on investments, success stories, and serial medical entrepreneur research. Mr. Phillips will contrast Canadian and US MedTech with insights from work with clients in both markets.

**Presenter:** Scott Phillips, BSc, Chief Executive Officer, StarFish Medical

#### Time: 3:25 to 4:10  
**Track:** Device Research

### Medical Device Directive (MDD): A Case Study Scenario on Clinical Evaluation of a Mechanical Circulatory Support (MCS) Device in Europe for CE Mark

Dr. Munjal will discuss requirements under the amended MDD for demonstration of the safety and clinical performance characteristics of the MCS device. Pertinent regulatory issues, considerations and strategies relating to critical evaluation of relevant scientific literature on a predicate device, if any, will be reviewed. The statistical analyses of data gathered from a prospective clinical study on the investigational MCS device including the side effects, along with the clinical claims and product labeling for submission to the Notified Body for approval of the CE Mark will be discussed.

**Presenter:** David Munjal, PhD, MSc, RAC, President, CRC Global Services, LLC
Accutest Research Laboratories

The regulatory scenario has drastically changed in India. Dr. Jani will give a few key insights into the present framework, current timelines, issues, etc. 315

Presenter: Ashutosh Jani, PhD, M.Pham, Head, Clinical Trials, Accutest Research Laboratories

Breakout Session Descriptions

Friday, September 30, 2016

**TRACK 2**

**Device Research**

Location: 520 c/f
Moderator: Kathi Durdon

**Time:** 4:15 to 5:00  
**Track:** Device Research

**FDA Approval of Humanitarian Use Devices**

Rare diseases collectively affect approximately 30 million Americans and more than 50% affect the pediatric population. However, relatively few medical devices have been developed to specifically address the needs of patients with pediatric or rare diseases. The Humanitarian Use Device/Humanitarian Device Exemption (HDE/HDE) is a unique marketing approval pathway for medical devices targeting diseases affecting small patient populations. This presentation will discuss lessons learned from an analysis of HDE approvals, needs assessment of devices for rare diseases, FDA device initiatives for rare diseases, and other relevant work in this field. 215

Presenter: Eric Chen, MS, Director, Humanitarian Use Device Designation Prog, Food and Drug Administration

**TRACK 3**

**International Trials and ICH**

Location: 520 b/e
Moderator: Anatoly Gorkun

**Time:** 1:15 to 2:00  
**Track:** International Trials and ICH

**Managing a Multinational NIH Study**

Ms. Thomas will discuss the regulatory requirements for conducting an NIH study in Asia, Europe, and US. 309

Presenter: Jessy Thomas, MS, Research Project Manager, University of Minnesota

**Time:** 2:05 to 2:50  
**Track:** International Trials and ICH

**The Changing Face of Clinical Research: Why Look to Central and Eastern Europe for Qualified Patients**

Many companies spend significant amounts of time and money trying to get patients enrolled in their clinical studies. Central and Eastern Europe (CEE) is a region that is still under-utilized as a venue for clinical research. Why should companies take another look at CEE? 311

Presenter: Jeffrey Blum, BS, Senior Director, Business Development, Intrinsic Imaging LLC

**Time:** 3:25 to 4:10  
**Track:** International Trials and ICH

**Clinical Trials in Africa - What to be Expected - a Case Study**

Cultural barriers, political upheaval and uneven infrastructure are certainly causes that might create problems in running a clinical trial in accordance with the Western world's legal and ethical expectations. However, Africa offers tremendous expertise and opportunity for cost-effective study sites and appropriate patient populations. What type of challenges are to be expected and how they have been overcome will be presented based on an HIV trial conducted in Nigeria. 313

Presenter: Gerhard Fortwengel, PhD, MPH, MSc, Professor, University of Applied Sciences and Arts, Hannover
Presenter: Sam Ibeneme, PhD, Senior Lecturer/Consultant Physiotherapist, University of Nigeria

**Time:** 4:15 to 5:00  
**Track:** International Trials and ICH

**The Current Regulatory Scenario in India**

The regulatory scenario has drastically changed in India. Dr. Jani will give a few key insights into the present framework, current timelines, issues, etc. 315

Presenter: Ashutosh Jani, PhD, M.Pham, Head, Clinical Trials, Accutest Research Laboratories

**TRACK 4**

**Data Management / EDC**

Location: 520 a/d
Moderator: Patricia Beers Block

**Time:** 1:15 to 2:00  
**Track:** Data Management / EDC

**Importance of a Detailed Statistical Analysis Plan in Clinical Study Report (CSR) Writing**

The presentation will address the importance of the statistical analysis plan and how detailed it should be, including the definition of analyzed populations, the statistical methodology used as well as derived data, the handling of missing data, and most importantly the definition of shells (Tables, Listings and Figures) as per ICH E3, to ease the development of each section of the CSR. 409

Presenter: Farida Dabouz, PhD, CCRP, President, FB2D Clinical Research Consulting Inc

**Time:** 2:05 to 2:50  
**Track:** Data Management / EDC

**eSource Beyond EDC and Data Management**

eSource is mainly discussed in the context of EDC and from a data management perspective. This may be due to the fact that the FDA guidance on electronic source data in clinical investigations focuses solely on EDC. However, the EMA made it clear in its reflection paper on GCP compliance in relation to trial master files that the concept of electronic source data needs also to be considered in other areas; for example, in the context of trial master files (TMF). This talk will provide an overview on the general aspects of eSource and how they apply to TMFs. 411

Presenter: Mathias Poensgen, PhD, Subject Matter Expert, Clinical, Aris Global

**Time:** 3:25 to 4:10  
**Track:** Behavioral Research

**The Language of Behavioral Clinical Trials: A Practical Thesaurus for Clinical Researchers**

Ms. Culp will give a brief introduction to the most common behavioral interventions tested in clinical trials to improve health, including those meant to educate, teach skills, and boost motivation. Using the drug-development paradigm as a foundation, the presenter will describe key steps in developing and testing behavioral interventions. Among the key steps to be discussed are protocol development, implementation, data capture, and quality control. Commonalities and differences between drug development and behavioral clinical trials will be highlighted. 413

Presenter: Michelle Culp, BSN, MPH, CCRP, RN, Director of Clinical Operations, National Center for Advancing Translational Science, NIH

**Time:** 4:15 to 5:00  
**Track:** International Trials and ICH

**The Current Regulatory Scenario in India**

The regulatory scenario has drastically changed in India. Dr. Jani will give a few key insights into the present framework, current timelines, issues, etc. 315

Presenter: Ashutosh Jani, PhD, M.Pham, Head, Clinical Trials, Accutest Research Laboratories
Breakout Session Descriptions

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<tr>
<th>TRACK 4</th>
<th>Behavioral Research</th>
<th>Location: 520 a/d</th>
<th>Moderator: Nancy Wintering</th>
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<tbody>
<tr>
<td>Time: 4:15 to 5:00</td>
<td>Track: Behavioral Research</td>
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<tr>
<td>Challenges in Behavioral Health Research in Health, Fitness, and Weight Management</td>
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<tr>
<td>The speaker will discuss challenges that are unique to behavioral health research that involve cognitive or behavioral change in health, fitness, and weight management. Challenges to be addressed include privacy, social stigma and reliability in self-reporting; interpersonal dynamics and how this may affect self-care and protocol compliance, impact of relationship dynamics in the participant's social support in the home and workplace; motivation in relation to incentives and behavior economics and whether the expected results are consistent with the subject's effort and readiness for change. Attendees will gain an understanding of challenges faced in behavioral health research and will be able to develop realistic study protocol procedures for future behavioral health interventions.</td>
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<tr>
<td>Presenter: Nancy Wintering, MSW, LCSW, CCRP, Research Program Manager, Thomas Jefferson University</td>
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<th>TRACK 5</th>
<th>Project Management</th>
<th>Location: 518</th>
<th>Moderator: Radhika Sivaramakrishna</th>
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<tr>
<td>Time: 1:15 to 2:00</td>
<td>Track: Project Management</td>
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<tr>
<td>Tools for Effective Project and Risk Management</td>
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<td>The overall goal of this session is to review a few tools/skills that will enhance one's project and risk management skills such as flow charts, Gantt charts, and risk registers. Having a clear understanding of these tools will allow a project manager to effectively manage clinical research resources and timelines including milestones and risks while properly linking them back to the project plan. Examples will be reviewed throughout the presentation.</td>
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<td>Presenter: Susan Leister, PhD, MBA, BS, CQA, CSSBB, Director of Quality Assurance, Technical Resources International, Inc.</td>
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<td>Time: 2:05 to 2:50</td>
<td>Track: Project Management</td>
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<td>Using PMI Project Management Principles When Considering a CTMS Implementation</td>
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<td>Implementation of a clinical trials management system at any site is a complex and risky endeavor. Using PMI project management principles and tools will fortify implementation and sustained success.</td>
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<td>Presenter: Elizabeth Micalizzi, MBA, CCRP, PMP, Director, Strategic Projects/Integrated Technology, Virginia Commonwealth University</td>
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<td>Time: 3:25 to 4:10</td>
<td>Track: Project Management</td>
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<td>Challenges and Benefits of Consortium Led Clinical Trials</td>
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<td>Collaborative efforts, combining expertise and oversight for clinical trials, are becoming more common. However, multi-organizational and multi-funder efforts provide their own inherent set of challenges and rewards. Adding in collaborators and sites from around the world only increases the scope of work and magnitude of challenges. Providing early and carefully laid out structure and expectations are key to success. Here, we explore the pros and cons of working in these large consortium efforts and outline some strategies for creating and maintaining successful structures that are linked to the success of the clinical trial.</td>
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<td>Presenter: Stephanie Combes, MA, CCRP, PMP, Program Manager, Bill &amp; Melinda Gates Foundation</td>
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<tr>
<td>Time: 4:15 to 5:00</td>
<td>Track: Project Management</td>
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<tr>
<td>Remaining OPTIMISTIC: Project Management for New Funding Mechanisms</td>
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<td>This talk will provide an overview of the Centers for Medicare and Medicaid Services Innovations grant as a newer funding mechanism and describe the differences from other traditional behavioral research studies. In addition, the presenter will describe unique project management tools and strategies to successfully manage a large, multi-facility implementation program funded by this mechanism.</td>
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<td>Presenter: Laura Holtz, BS, CCRP, Senior Research Manager, IU Ctr for Aging Research, Regenstrief Institute</td>
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<th>TRACK 6</th>
<th>Pediatric Research</th>
<th>Location: 519</th>
<th>Moderator: Susan Devine</th>
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<tr>
<td>Time: 1:15 to 2:00</td>
<td>Track: Pediatric Research</td>
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<tr>
<td>Pediatric Clinical Research: Informed Consent and Assent Considerations for High Risk Studies</td>
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<td>Ms. Talley will explore the ethics involved in having children participate in studies that may be invasive, high risk, early phase, or where children have limited understanding or diminished cognitive capacity. Human subject protections regarding children participating in clinical research, with special attention given to the informed consent and assent process, will be reviewed. The rationale of why children should be included in clinical trials and the many factors that can influence participation will be explored.</td>
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<td>Presenter: Christina Talley, MS, CCRP, RAC, Prog Director, Office of Strategic Res Initiatives, Houston Methodist Research Institute</td>
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<td>Time: 2:05 to 2:50</td>
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<td>Justifying the Choice of a Control Arm in Pediatric Clinical Trials</td>
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<td>An evidence-based tool to justify the selection of a control arm (placebo, active) in pediatric clinical trials will be presented. Dr. Kelly will discuss the challenges in selecting a control arm in pediatric trials using real empirical data on evaluated Pediatric Investigation Plans adopted by the European Medicines Agency.</td>
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<td>Presenter: Lauren Kelly, PhD, MSc, BMSc, CCRP, Postdoctoral Fellow, Hospital for Sick Children</td>
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<td>Time: 3:25 to 4:10</td>
<td>Track: Pediatric Research</td>
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<tr>
<td>Conducting Pediatric Clinical Trials with Rare Diseases</td>
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<td>Managing pediatric clinical trials for patients with rare diseases takes special consideration. This presentation will discuss the challenges of early detection of rare diseases, recruitment and retention issues, and the impact on family life. The speaker will explore the best ways to serve the patients and their families.</td>
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<td>Presenter: Candice Roush, BSN, RN, CCRC, Research Nurse, The Research Institute at Nationwide Children's Hospital</td>
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<tr>
<td>Presenter: Shelli Farley, ADN, RN, CCRC, Clinical Research Nurse, The Research Institute at Nationwide Children's Hospital</td>
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**Breakout Session Descriptions**

Friday, September 30, 2016

**TRACK 6**
**Pediatric Research**
Location: 519
Moderator: Susan Devine

**Time:** 4:15 to 5:00

**Track: Pediatric Research**

**Recruiting Healthy Controls in the Pediatric Population**

This session is aimed at site staff that will be engaged in or looking to start projects that involve healthy controls. The speakers will discuss the importance of enrolling healthy controls and tactics for successful study completion. Objectives include defining why healthy controls are critical in pediatric research, identifying recruitment strategies in the healthy control population, and discussing challenges when recruiting healthy children. 615

Presenter: Jessica Estep, BSN, RN, CPN, Clinical Research Nurse Coordinator, The Research Institute at Nationwide Children’s Hospital

**TRACK 7**
**Ethics in Research**
Location: 516 c/d
Moderator: Tammy Neseth / Jaime Harper

**Time:** 1:15 to 2:00

**Track: Ethics in Research**

**Working to Eliminate Disparities in Clinical Trials: One Site’s Experience**

Dr. Jackson will achieve the following four objectives: 1) Explain why inclusion of minorities is critical in clinical research; 2) Describe legislative background such as the NIH Revitalization Act and its amendments; 3) Provide examples of what some funding agencies expect of minority inclusion in trials; and 4) Review a large clinical study site’s challenges in and potential solutions to meeting inclusion requirements. 709

Presenter: Jonathan Jackson, PhD, Instructor, Harvard Medical School

**Time:** 2:05 to 2:50

**Track: Ethics in Research**

**Revisiting the Syphilis Study: What Really Happened at Tuskegee?**

From 1932 to 1972, a study entitled “Untreated Syphilis in the Negro Male” was conducted in Macon County, Alabama on 600 subjects to examine the natural progression of syphilis. The study was funded by the US Public Health Service but is widely used as an example of unethical treatment of human research subjects. The incident has been described in numerous venues over the years, and the details of the study have consequently taken on inconsistent iterations. This talk will revisit the details of the study and extrapolate what its true impact was then and continues to be on the human subjects’ research landscape. 711

Presenter: Quincy Byrdsong, EdD, CIM, CCRP, CIP, VP for Academic Planning & Strategic Initiatives, Augusta University

**Time:** 3:25 to 4:10

**Track: Ethics in Research**

**Ethical Considerations in Consenting for Lab Protocols**

Ms. Tse will discuss the implications of consent for tissue as well as court proceedings over tissue donation and use. True informed consent and medical trends will also be presented. 713

Presenter: Susan Tse, BSN, RN, CCRP, Research Nurse Manager, UT MD Anderson Cancer Center

**Time:** 4:15 to 5:00

**Track: Ethics in Research**

**Research with Respect: Family Advocacy in Pediatric Clinical Trials**

The presenters will discuss the ethical considerations for working with families enrolled in pediatric clinical trials. Maintaining respect for the autonomy of families is a vital aspect toward achieving best outcomes. We will principally focus on the importance of advocating for the special needs of the family unit, traditional and non-traditional alike. Further, we will discuss the significance of providing valuable resources to families, and how this can positively affect recruitment and retention rates. 715

Presenter: Lauren Bird, BA, BSN, RN, CCRP, Clinical Research Nurse, The Research Institute at Nationwide Children’s Hospital

**Time:** 1:15 to 2:00

**Track: GCP Audit Preparedness**

**Investigator/Investigational Site Responsibilities**

The participants will learn how to handle the FDA inspection and prepare study documents if their site is selected for an audit. The responsibilities and commitments of the site will be discussed. Additionally, Mr. Rashti will explain the most common deficiencies observed during an audit, how to avoid them, and how to be in compliance with the GCP regulation. 809

Presenter: Mike Rashti, BS, President, BIMO Auditor and Trainer, LLC

**Time:** 2:05 to 2:50

**Track: GCP Audit Preparedness**

**Preparing for Successful Sponsor Audits**

It’s time to view the sponsor’s auditor as a colleague who can help you be the best site you can be. Ms. Kelley will cover topics such as what you should prepare in advance of an audit, how to avoid them, and how to be in compliance with the GCP regulation. 811

Presenter: Lauren Kelley, BA, CCRP, Associate Director, GCP Compliance, Polaris Compliance Consultants Inc

**Time:** 3:25 to 4:10

**Track: Risk Management**

**Risk Management: How Are Sponsors Managing Risk?**

This presentation will focus on what the industry, especially sponsors, are doing to manage risks during clinical trials. Ms. Malia will touch upon various industry initiatives, such as Transcelerate BioPharma and what they are doing or advocating and how this is being put into practice by large and small sponsors. The presenter will suggest ways sponsors and sites may work together to manage risks to the benefit of patient safety and data quality. 813

Presenter: Joanne Malia, BS, MS, Independent Consultant

**Time:** 4:15 to 5:00

**Track: Risk Management**

**Implementing Quality by Design in Clinical Trials**

The presentation will review some misconceptions of quality, then take the audience on a step-by-step journey on how to implement proper quality by design techniques into their clinical trial project. Mr. Bartekian will discuss quality philosophies, quality issues normally encountered at sites and CROs, and practical ways to build quality into a program in order to prevent issues. The presenter will describe the FDCA cycle (Plan-Do-Check-Act) and tie it in with risk-based monitoring. 815

Presenter: Vatche Bartekian, BSc, MSc, President and Founder, Vantage BioTrials, Inc.
### Breakout Session Descriptions

#### TRACK 1

<table>
<thead>
<tr>
<th>Session Title</th>
<th>Location</th>
<th>Track:</th>
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<th>Moderator(s)</th>
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<tbody>
<tr>
<td><strong>Poster Session</strong></td>
<td>524</td>
<td><strong>Poster</strong></td>
<td>8:30 to 10:05</td>
<td>Bryce Warren and Joanne Goldberg</td>
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<tr>
<td><strong>Poster Session Presentations</strong></td>
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<tr>
<td>Selected poster presenters will present a synopsis of their work related to Clinical Trials and Clinical Trials Management.</td>
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<tr>
<td>Presenter: Joanne Goldberg, MSc, CCRP, Assistant Director, CIHR Institute of Aging</td>
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<tr>
<td>Presenter: Bryce Warren, PhD, Chairman, L. H. Warren Foundation for Science</td>
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<tr>
<td><strong>Responsible Conduct of Research</strong></td>
<td>524</td>
<td><strong>Training</strong></td>
<td>10:50 to 11:35</td>
<td>Mariah Tackett</td>
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<tr>
<td><strong>Case Studies in the Responsible Conduct of Research</strong></td>
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<td>Dr. Cookmeyer will use case studies and lessons learned to discuss research integrity and the consequences of a scientific enterprise that relies solely on a “self-correcting” model of peer review and independent validation of results. An updated model of actively promoting research integrity and encouraging the safe reporting of problems will be presented that is based on tools and strategies adopted from the patient safety movement and a “just culture.” Approaches will be discussed for moving beyond a “reactive” mode of responding to questionable research practices and more serious issues of research misconduct to a “proactive” setting where all components of the research enterprise are involved in, responsible for, and accountable to a community standard of integrity. This session will focus on remediation not only of individual issues but also of factors in the institutional setting where questionable practice or misconduct may have been facilitated or gone undetected will be discussed.</td>
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<tr>
<td>Presenter: John Kessler, PharmD, BCPS, Chief Clinical Officer, SecondStory Health, LLC</td>
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<th>Location</th>
<th>Track:</th>
<th>Time:</th>
<th>Moderator(s)</th>
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<tbody>
<tr>
<td><strong>Nurse as Researcher</strong></td>
<td>524</td>
<td><strong>Poster</strong></td>
<td>12:40 to 12:55</td>
<td>Cheryl Chanaud</td>
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<tr>
<td><strong>Want to Write a Research Protocol? What to Consider, Where to Start &amp; How to Create a Protocol Draft</strong></td>
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<tr>
<td>Dr. Mick will provide information on the purpose and components of a research protocol and helpful strategies for writing a protocol draft with an Institutional Review Board reviewer's perspective in mind. Three steps to writing an abstract, the difference between a study purpose and research question, and how to synthesize a review of literature that includes justification for conducting a study will be described. Other information will include a description of a critical thinking path for selecting appropriate data collection methodologies, describing risks and benefits to human subjects, and inclusion of a dissemination plan in study design.</td>
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<tr>
<td>Presenter: JoAnn Mick, PhD, RN, NEA-BC, Nurse Researcher, Memorial Hermann - Texas Medical Center</td>
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<tr>
<td><strong>Nurse as Researcher</strong></td>
<td>524</td>
<td><strong>Training</strong></td>
<td>3:45 to 4:30</td>
<td>Anatoly Gorkun</td>
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<tr>
<td><strong>Important Insights for Team Building within Clinical Trials in Oncology</strong></td>
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<tr>
<td>Ms. Grant will explore approaches to team building in the workplace with a focus on adult education principles. Insights learned from teaching and leading clinical research personnel within a large Canadian oncology centre will be shared. The audience will be invited to join in on an interactive discussion so that we can learn from each other's experiences.</td>
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<tr>
<td>Presenter: Jasmine Grant, Med, BHSc, CCRP, Education Specialist Lead, Princess Margaret Cancer Centre</td>
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<td>1:40 to 2:25</td>
<td>Cheryl Chanaud</td>
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<tr>
<td><strong>The Journey from Point A to Point B: How to get from Clinical Inquiry to Conducting Nursing Research</strong></td>
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<td>This presentation will define three types of clinical inquiry: evidence based practice (EBP), quality improvement (QI), and research. Steps nurses can take to move from having a practice idea or question to making a decision about conducting nursing research will be described. Information provided will include how to identify a problem/topic, how to view a problem/topic from a variety of practice angles, key sources of evidence to consider when conducting a literature review, making a decision to conduct research, and steps of the research process. The role of nurses in EBP, quality improvement, and research will be described in terms of how nurses can contribute to the body of knowledge that guides nursing practice.</td>
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<tr>
<td>Presenter: Barbara Gladson, PhD, PT, OT, Associate Dean for Academic Affairs Rutgers School of Health Professionals</td>
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**Saturday, October 1, 2016**

**SOCRA 2016 Annual Conference Program**
Human factors simulated-use studies provide a valuable tool for evaluating the usability and safety of medical devices, including combination products such as pre-filled syringes, pens, nasal sprays and inhalers. Human factors studies enable researchers to evaluate how users and devices perform in low frequency, high risk situations that may not occur in controlled clinical trials. This talk will provide an overview of the role of human factors testing in combination product development and how human factors studies complement traditional clinical trials in establishing drug and device safety and efficacy.

Presenters: Tim Reeves, PhD, CHFP, Founder and Managing Director, Human Factors MD Inc

Time: 9:20 to 10:05

Medical Device Clinical Trials: A Canadian Perspective

Conducting medical device clinical trials in Canada according to the regulations is critical to the outcome of the clinical investigation. In Canada, medical devices are regulated by Health Canada and classified according to Health Canada’s risk-based system. An overview of Canadian Regulations will be presented with emphasis on Health Canada’s Classification System. The International Organization for Standardization (ISO) 14155:2011 and the process for submitting an Investigational Testing Authorization (ITA) to Health Canada to conduct a clinical trial will be discussed.

Presenters: Valerie Cronin, BA, MA, CCRP, RN, SCM, Clinical Nurse Research Coordinator, The Ottawa Hospital, Kidney Research Centre

Time: 10:50 to 11:35

Experiences of Monitoring via Remote Access to Electronic Medical Records

Remote monitoring is the wave of the future. Medical facilities are now required to use an electronic medical records system. Most research studies use electronic data capture/remote data capture systems instead of the paper case report forms. With many electronic medical record systems, sponsors now have the ability to monitor studies remotely. Sites’ IT departments assign ID/passwords and a link to the monitor and give monitors read-only access to a cohort of study patients. The cohort of patients is requested by the coordinator, and with the link/ID/password can be monitored without the field CRA having to travel to the site. Remote monitoring decreases travel costs for the sponsor, and assists the sites by not having to keep office space available for field monitors. Remote monitoring can also be done by in-house CRAs so that adverse events may be reviewed more quickly, as well. Remote monitoring is time saving and cost effective.

Presenters: Kristi Pinkston, BS, MA, CCRP, RN, Sr Field Clinical Research Associate, St Jude Medical, Inc.

Time: 11:40 to 12:25
Breakout Session Descriptions

<table>
<thead>
<tr>
<th>Time: 8:30 to 9:15</th>
<th>Track: Canadian Regulations / Inspections</th>
<th>Negotiating Canadian Clinical Trial Agreements: Key Issues and Practical Tips</th>
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</thead>
<tbody>
<tr>
<td>This session will address key elements to consider when reviewing and negotiating a clinical trial agreement involving a Canadian site, including ensuring you have properly bound all applicable parties and how to ensure your CTA does not jeopardize the PI's medical malpractice coverage or the site's insurance coverage. Mr. Rajakaruna will explain why governing law and jurisdiction language really matter and why you need to understand local laws. 317</td>
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<tr>
<td>Presenter: Marlon Rajakaruna, BA, MBA, LLB, CRCP, Partner, Global &amp; Nat'l Co-Leader of Life Sciences, Dentons Canada LLP</td>
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<tr>
<th>Time: 9:20 to 10:05</th>
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<tr>
<td>Inspection of Clinical Investigator: Conducting Clinical Trials in Canada</td>
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<tr>
<td>Controlled Substances in Clinical Research: Perspectives from an Academic Research Centre</td>
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<tr>
<td>This presentation will give the attendees a greater understanding of the regulatory framework surrounding the use of controlled substances in research, provide guidance regarding completion and submission of a Controlled Drugs and Substances Act Section 56 Exemption and learn about drug sourcing and importation procedures for academic investigations. 321</td>
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<tr>
<td>Presenter: Gregory Staios, MSc, CCRP, Research Monitor, Centre for Addiction and Mental Health</td>
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<tr>
<td>Why I Believe in Testimonials</td>
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<tr>
<td>Mr. Tully will present a first-hand experience of the role a clinical trial played when a loved one was threatened by a terminal illness. This is an intimate view of participating in a clinic study and how it impacts the patient and family. 323</td>
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<tr>
<td>Presenter: Marty Tully, Publisher,</td>
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<th>Time: 1:40 to 2:25</th>
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<tr>
<td>GCP Compliance Program</td>
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<tr>
<td>Ms. Kasina will discuss frequent compliance questions and highlight more recent initiatives. 325</td>
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<tr>
<td>Presenter: Alicja Kasina, MSc, PhC, Drug Specialist, Health Canada</td>
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Time: 3:45 to 4:30  Track: Canadian Regulations / Inspections  Practical Applications of the Initiative to Streamline Clinical Trials

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<th>Time: 4:35 to 5:20</th>
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<tr>
<td>Streamlining and Promoting Clinical Trials in Canada - the CCTCC</td>
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<tr>
<td>Researchers from across Canada came together to create the Initiative to Streamline Clinical Trials, a document that provides ideas for making clinical research easier while maintaining participant safety and the scientific integrity of the study. The Initiative was made public in the spring of 2014, and Ms. Bosch will focus on the uptake of information in the Canadian clinical trials community as well as suggestions for improvement and for further streamlining. 329</td>
</tr>
<tr>
<td>Presenter: Jackie Bosch, PhD, MSc, BSc., Director, Project Management, PHRI, Population Health Research Institute / McMaster University</td>
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Time: 2:30 to 3:15  Track: Canadian Regulations / Inspections  “Lost in Translation” - Conducting Transnational Research in Canada and the United States

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<tr>
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<tr>
<td>Streamlining and Promoting Clinical Trials in Canada - the CCTCC</td>
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<tr>
<td>There is global competition for attracting clinical trials. The objective of this presentation is to present a pan-Canadian initiative for promoting Canada as a leading destination for clinical trials—the Canadian Clinical Trials Coordinating Centre (CCTCC). The CCTCC is a unique collaborative initiative funded by industry represented by Innovative Medicines Canada (formerly Rx&amp;D), government represented by the Canadian Institutes of Health Research (CIHR) and academia represented by HealthCareCAN. The CCTCC is coordinating a number of projects to streamline the conduct of clinical trials in Canada. Its most notable outcomes to date are the Model Clinical Trials Agreement (mCTA) and the Canadian Clinical Trials Asset Map (CCTAM). Join Ms. Aminkova to learn more about how the mCTA, CCTAM and otherCCTCC's projects contribute to strengthening the Canadian clinical trials environment and showcasing globally recent Canadian clinical trial operational efficiencies and advances. 331</td>
</tr>
<tr>
<td>Presenter: Elena Aminkova, MA, Interim Director of Project Facilitation, Canadian Clinical Trials Coordinating Centre</td>
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## TRACK 4
### Complementary and Alternative Medicine
Location: 520 a/d  
Moderator: Nancy Wintering

**Time:** 8:30 to 9:15  
**Track:** Complementary and Alternative Medicine

**FDA and Health Canada Perspectives on Homeopathic Products as Drugs**

Homeopathic products are widely used in the US and Canada. Homeopathic products in the US are regulated as drugs; in Canada they are regulated as natural health products. In traditional medicine pharmacologically active agents are used to suppress symptoms or pathophysiologic processes of diseases. The treatment of disease in homeopathic medicine is to use diluted substances that produce symptoms in healthy individuals similar to those of the diseases that they treat. Scientific and regulatory similarities and differences will be presented for discussion.  

**Presenter:** Harvey Arbit, PharmD, MBA, CCRP, RAC, President, Arbit Consulting, LLC

**Time:** 9:20 to 10:05  
**Track:** Complementary and Alternative Medicine

**When There Is No Place to Turn, I’ll Try Integrative Medicine Research Too**

Integrative medicine and CAM research is sought by persons facing potentially devastating illnesses. Ms. Wintering will discuss integrative medicine research conducted with persons with Alzheimer’s disease, Parkinson’s disease and Cancer. Project planning, collaboration, risk management and psychological considerations will be presented. Challenges and opportunities for successful integrative medicine research will be discussed.  

**Presenter:** Nancy Wintering, MSW, LCSW, CCRP, Research Program Manager, Thomas Jefferson University

## TRACK 4
### Monitoring
Location: 520 a/d  
Moderator: Angela Rock

**Time:** 11:40 to 12:25  
**Track:** Monitoring

**The Sawyer Effect: Impacting Recruitment from a Sponsor/CRO Perspective**

As clinical trials become increasingly complex, looking to recruit a more selective patient, and draw more conclusions, an increased load has been placed on the site staff. This often translates into sluggish recruitment and site demotivation. With over 80% of clinical trials not meeting recruitment targets, change is overdue in how sponsors and CROs approach the topic of patient recruitment. In this presentation, psychology and evidence based research reveal what truly motivates clinic site staff, from study coordinators to principal investigators. Scientists have recognized the importance of intrinsic motivation for decades. The shifting paradigm in clinical research will be discussed, as the traditional “fact checking” CRA becomes the site manager. The shift to a “heads up” approach to site monitoring and management will allow CRAs to begin to build these principals of intrinsic motivation into their relationship with sites, resulting in more productive clinical sites.  

**Presenter:** Fraser Gibson, BSc, CCRP, CCRA, President, Advantage Clinical

**Time:** 1:40 to 2:25  
**Track:** Monitoring

**Why Does this Problem Keep Happening Over and Over?**

In examining clinical trial findings, we may discover that very often they highlight the same type of problems which arise year after year. Have you ever wondered why the same issues occur repeatedly despite the implementation of quality systems, compliance training, and CAPA plans? Dr. Gorkun will look into the root cause and make sure the corrective and preventative actions are addressing the actual problem rather than its symptoms. Case study examples will be provided. This presentation was developed in collaboration with April Bishay, Senior Manager Clinical Compliance at MedImmune.  

**Presenter:** Anatoly Gorkun, MD, PhD, Chartered MCIPD, Senior Manager, Scientific & Compliance Training, MedImmune

**Time:** 2:30 to 3:15  
**Track:** Monitoring

**Risk-Based Monitoring - Is Everyone on the Same Page?**

Ms. Boakye will present a review to assess if CRO, pharma, and academia are all seeing if risk-based monitoring is truly transforming clinical trials and if they are cohesive in their approach.  

**Presenter:** Golda Boakye, MSc, BSc, CCRP, Clinical Team Manager/Consultant, PRAHS/Naantu Research, Inc

**Time:** 3:45 to 4:30  
**Track:** Monitoring

**BULLSEYE: What is Targeted Monitoring All About?**

“Targeted monitoring” has become a popular catch phrase. Where did it come from? What is targeted monitoring all about, and how is it done? Is it any good? Come hear a monitor’s experience with this newfangled way of doing source/data verification.  

**Presenter:** Jane Ferguson, RN, MSN, CCRP, Senior Clinical Research Associate, Westat
BREAKOUT SESSION DESCRIPTIONS

Saturday, October 1, 2016

**TRACK 4**

**Monitoring**

Location: 520 a/d

Moderator: Mariah Tackett

**Time:** 9:20 to 10:05

**Track:** Monitoring

Remote Monitoring - How Can a Data Warehouse Help?

The presentation summarizes a research project at Medical School Hannover. The objectives of the project are to investigate options for remote monitoring activities, in particular related to data verification and identification of safety issues, both mainly in IITs. The internal data warehouse is used as basis to validate data and to reconcile safety information as reported in the trials. The research project is ongoing and will be completed by April 2016. 431

Presenter: Gerhard Fortwengel, PhD, MPH, MSc, Professor, University of Applied Sciences and Arts, Hannover

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**TRACK 5**

**Advanced Management**

Location: 518

Moderator: Lisa Benson / Ruben Rodarte

**Time:** 3:45 to 4:30

**Track:** Advanced Management

The Process of Conducting Emergency Protocols

Ms. Larson will discuss how we brought up multiple emergency protocols and treated patients with an investigational drug within 24 hours of receiving notice of their arrival. Discussion will include but not be limited to emergency INDs, calling an emergency IRB meeting, getting an IRB application/consent written in <24 hours, developing source documents, study drug administration in a biocontainment unit, special consenting issues, how to get data out of a biocontainment unit, and sharing data. 529

Presenter: LuAnn Larson, BSN, RN, Director of Clinical Research Operations, University of Nebraska Medical Center

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**Time:** 8:30 to 9:15

**Track:** Advanced Management

Adding It All Up to Create the Perfect Balance: Advanced Site Management Tools

Ms. Talley will examine the rationale for implementing a detailed protocol analysis, feasibility assessment, and how that translates to scaling for site workload distribution or personnel needs. She will review current protocol and research analysis and scoring models, and introduce a non-cancer based scoring model. How assessments of protocol complexity, workload, and personnel needs that can impact financial resource allocation will be discussed. 517

Presenter: Christina Talley, MS, CCRP, RAC, Prog Director, Office of Strategic Res Initiatives, Houston Methodist Research Institute

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**Time:** 2:30 to 3:15

**Track:** Advanced Management

Simple Data Gathering Tools Can Greatly Improve Research Quality Management

In order to manage the diverse activities that make up a clinical research program, it is essential to be able to identify trouble spots, assess and correct deficiencies, and continually monitor process improvements for efficacy. While this can seem like a monumental task, it can be broken down into simple constituent steps. This can be carried out with a minimal expenditure of effort and without the purchase of expensive custom software packages. This session will demonstrate a process for developing simple tools to leverage existing information, organize collection of additional information, analyze the data set, and drive lasting improvements using standard office productivity software. 527

Presenter: Rebecca McCue, BA, Associate Director, Site-Based Research, Stanford University School of Medicine

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**Time:** 4:35 to 5:20

**Track:** Monitoring

**Time:** 11:40 to 12:25

**Track:** Advanced Management

**Time:** 1:40 to 2:25

**Track:** Advanced Management

**Time:** 2:30 to 3:15

**Track:** Advanced Management

**Time:** 3:45 to 4:30

**Track:** Advanced Management

**Time:** 10:50 to 11:35

**Track:** Advanced Management

**Time:** 8:30 to 9:15

**Track:** Advanced Management
### TRACK 5
**Advanced Management**
**Location: 518**  
**Moderator: Ruben Rodarte**

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<th>Time: 4:35 to 5:20</th>
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<tr>
<td><strong>Identifying Effective Community Consultation Methods for 21 CFR 50.24 Compliance</strong></td>
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Research in emergency environments involves interventions administered to patients at a time when no intervention may result in death or permanent disability. In these circumstances, patients are considered vulnerable since they may be unconscious, in shock and alone. These are not the ideal conditions to obtain informed consent from the patient. In order to address these issues the FDA and DHHS introduced 21 CFR 50.24, entitled Exception from Informed Consent (EFIC) for Emergency Research. The regulation is vague and researchers use various methods to conduct community consultations as a means to engage the community's opinions prior to conducting emergency research. This presentation will review current published methods of community consultation including an in-depth look at the purpose and intention of community consultations as they apply to 21 CFR 50.24, the methods utilized, and their effectiveness in communicating with the appropriate potential target study population and potential improvements to the current processes.  

*Presenters: Skeeta Sobrian, BHA, MScHQ, CCRP, RN, Consultant, ReQue*

### TRACK 6
**Oncology Research**
**Location: 519**  
**Moderator: Susanna Sellmann**

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<th>Time: 10:50 to 11:35</th>
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<tr>
<td><strong>Moving Beyond Paper: Implementing an Electronic Source (eSource) Platform</strong></td>
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Ms. Cole will share the Princess Margaret Cancer Centre's experience of implementing an electronic source (eSource) system; the process, challenges, and advantages of working electronically.

*Presenter: Heather Cole, BSc, Manager, Cancer Clinical Research Unit, Princess Margaret Cancer Centre*

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<td><strong>The University Health Network Genitourinary (GU) BioBank</strong></td>
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Since the date of its inauguration in 2008, the GU BioBank has accrued hundreds of thousands of specimens from more than 10,000 consenting patients. The GU BioBank aims to facilitate the discovery of new diagnostic and prognostic biomarkers to achieve the ultimate goal of personalized medicine and improved outcomes for GU oncology patients. The GU BioBank has garnered an incredible amount of interest in recent years, and we would like to share our experience in setting up and maintaining this patient-centered research program. Ms. Laszlo will touch on biobanking challenges including but not limited to data quality (accuracy and completeness).

*Presenter: Sanda Laszlo, MHM, CCRP, GU BioBank, QA, & Projects Lead, UHN, Princess Margaret Cancer Centre*

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<tr>
<td><strong>Methods for 21 CFR 50.24 Compliance</strong></td>
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Identifying Effective Community Consultation

Research in emergency environments involves interventions administered to patients at a time when no intervention may result in death or permanent disability. In these circumstances, patients are considered vulnerable since they may be unconscious, in shock and alone. These are not the ideal conditions to obtain informed consent from the patient. In order to address these issues the FDA and DHHS introduced 21 CFR 50.24, entitled Exception from Informed Consent (EFIC) for Emergency Research. The regulation is vague and researchers use various methods to conduct community consultations as a means to engage the community's opinions prior to conducting emergency research. This presentation will review current published methods of community consultation including an in-depth look at the purpose and intention of community consultations as they apply to 21 CFR 50.24, the methods utilized, and their effectiveness in communicating with the appropriate potential target study population and potential improvements to the current processes.  

*Presenters: Skeeta Sobrian, BHA, MScHQ, CCRP, RN, Consultant, ReQue*

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<th>Time: 10:50 to 11:35</th>
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<tr>
<td><strong>Trends Utilizing a Web-Based Data Capture System</strong></td>
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Identifying and Validating Recruitment and Retention Trends Utilizing a Web-Based Data Capture System

Ms. Hoeper will demonstrate how the transition from using Excel spreadsheets to a secure web-based data capture system assisted in early identification of trends that hinder the recruitment process leading to improvements to the overall study conduct.

*Presenter: Amy Hoeper, MSN, RN, CCRC, Quality Manager, Gamble Program for Clinical Studies, Cincinnati Children's Hospital Medical Center*

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<th>Time: 11:40 to 12:25</th>
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<tr>
<td><strong>The Role of the Specialized Oncology Nurse in Clinical Trials</strong></td>
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This session will provide an overview of applying the ambulatory model of nursing care to clinical oncology as well as training and orientation of new trial nurses. Strategies for working with clinical staff, provisions of protocol training for supporting departments, and transfer of accountability will also be discussed. Finally, innovations in clinical trial nursing that have been implemented at Princess Margaret Cancer Centre will be reviewed.

*Presenter: Julie Gundry, MSc(A), CCRP, RN, Advanced Practice Nurse Educator, Princess Margaret Cancer Centre*

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<th>Time: 1:40 to 2:25</th>
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<tr>
<td><strong>Identifying and Validating Recruitment and Retention Trends Utilizing a Web-Based Data Capture System</strong></td>
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Ms. Hoeper will demonstrate how the transition from using Excel spreadsheets to a secure web-based data capture system assisted in early identification of trends that hinder the recruitment process leading to improvements to the overall study conduct.

*Presenter: Amy Hoeper, MSN, RN, CCRC, Quality Manager, Gamble Program for Clinical Studies, Cincinnati Children's Hospital Medical Center*

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<th>Time: 2:30 to 3:15</th>
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<tr>
<td><strong>Narrow the Focus - Open the Aperture</strong></td>
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“The protocol says this, my study team wants that, and my study participant needs something else; so where do I even begin to know where to start?” Surprisingly the starting point is not the protocol or your team but the study participant. The new CRC need not become overwhelmed by everything that everyone says, wants, or needs done and done NOW. By narrowing the focus to the primary objective of protecting the study participant and then the study team the CRC will then be better able to open the aperture of prioritizing tasks to meet the protocol's parameters.

*Presenter: Jennifer Kay, BSN, RN, CCRP, CCRC, Clinical Research Coordinator, University of Virginia Health System*
### TRACK 6
**Enrollment**

**Location:** 519  
**Moderator:** Lenore Jackson-Pope

**Time:** 3:45 to 4:30  
**Track:** Enrollment

**Recruitment and Retention in Pediatric Clinical Research: Strategies for Success**

The recruitment, enrollment, and retention of subjects is a challenge and remains one of the most difficult and rate-limiting step for all studies. The objectives of this presentation are to discuss various methods for successful and timely recruitment of participants for clinical studies, as well as which strategies to employ to increase retention of those subjects. 629

**Presenter:** Munaza Jamil, BSc, CCRA, CCRP, Clinical Trials Manager, North York General Hospital

**Time:** 4:35 to 5:20  
**Track:** Enrollment

**Challenges and Strategies for Subject Recruitment**

The presentation will consider the changes and challenges in clinical trials that are impacting subject recruitment and how to get the “message” to potential subjects. We will discuss how to determine appropriate recruitment strategies, discuss and demonstrate how to measure subject recruitment performance, and discuss strategies for sourcing and communicating with subjects including the use of social media. The methodology for subject retention will be evaluated. 631

**Presenter:** Kathy Godfrey, Instructor/Clinical Coordinator, Seneca College/Cardiac Care Network of Ontario

**Presenter:** Sabrina Ramkellawan, CCRP, CCRA, RN, Vice President of Operations, Apollo Applied Research

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### TRACK 7
**Informed Consent**

**Location:** 516 c/d  
**Moderator:** Wendy Lloyd

**Time:** 3:45 to 4:30  
**Track:** Informed Consent

**Informed Consent: Participants Just Don’t Understand….or Do They?**

This presentation will discuss one institution’s experience in implementing institutional-wide simplified ICFs. 717

**Presenter:** Michelle Dickey, MS, FNP-BC, PNP-BC, CCRC, Assistant Professor, Nurse Manager, Cincinnati Children’s Hospital Medical Center

**Presenter:** Tara Foltz, ASN, BA, RN, CRN, CCRC, Senior Clinical Research Nurse, Cincinnati Children’s Hospital Medical Center

**Time:** 4:35 to 5:20  
**Track:** Informed Consent

**Informed Consent, Clinical Trials, and Interpreters**

Ample literature acknowledges language barriers in standard care of practice. However, there is an acute shortage of research on communication barriers during the informed consent process in clinical trials. To contribute to the growing need to address Limited English Proficiency (LEP) in health care, a qualitative case study was used to explore communication methods and the understanding of LEP guardians of pediatric patients while participating in the informed consent process during clinical trials. 719

**Presenter:** Roberto Torres, DHA, President, TRS Clinical

**Time:** 5:25 to 6:10  
**Track:** Informed Consent

**Exception from Informed Consent: EFIC**

Trauma patients in an emergent situation usually do not have the ability to consent nor are their legally authorized representatives (LAR) available. Their life-threatening medical condition necessitates urgent intervention before consent can be obtained. A trauma

(cont’d on next column)

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### TRACK 7
**IRB - Solutions - Methods**

**Location:** 516 c/d  
**Moderator:** Quincy Byrdsong

**Time:** 3:45 to 4:30  
**Track:** IRB Issues - Solutions - Methods

**The Ins and Outs of IRB Reliances**

Ms. Gates will describe IRB reliances from start to finish. This session is really needed given the expected NIH Mandate for single IRB review. Issues to be covered include: types of reliances, agreements, reviewing IRB requirements, relying IRB requirements. 729

**Presenter:** Cynthia Gates, JD, ADN, CCRP, CIP, Director, IRB Administration, University of California, Davis
### Breakout Session Descriptions

**TRACK 7**  
**IRB - Solutions - Methods**  
**Location:** 516 c/d  
**Moderator:** Quincy Byrdsong  
**Time:** 4:35 to 5:20  
**Track:** IRB Issues - Solutions - Methods  
**How to Eliminate Overreporting**  
IRBs continue to be overburdened with reports not required by federal regulation. It is important to understand what is required by regulation and what has become an industry standard. Additionally, study sites are often confused regarding reporting requirements and err on the side of conservatism by overreporting. By clearly identifying regulatory requirements versus what has become standard operating procedure, our industry may well become more efficient and eliminate unnecessary work for sites as well as IRBs. 821  
**Presenter:** Sarah Attwood, BSc, Director of Business Development, IntegReview IRB

### TRACK 8  
**Quality Management**  
**Location:** 516 a/b  
**Moderator:** Radhika Sivaramakrishna  
**Time:** 8:30 to 9:15  
**Track:** Quality Management  
**Research Quality Audits: Internal Risk-Based Auditing in a Large Academic Research Hospital**  
This talk will outline the development of an internal research quality audit process for clinical trials conducted in an academic research hospital. An overview of the research quality audit objectives, selection process, audit procedures, audit report, and follow-up will be provided. Ms. Marzinotto will also discuss the role and expectations of the researcher in the conduct of quality research. 817  
**Presenter:** Velma Marzinotto, BScN, RN, CCRP, Senior Research Compliance & Education Specialist, St. Michael’s Hospital  
**Time:** 9:20 to 10:05  
**Track:** Quality Management  
**Inspection Findings Related to the Informed Consent Procedure: Lessons Learned**  
Informed consent irregularities remain one of the leading findings in FDA and EMA inspections. In this session, we will examine real-world examples of FDA informed consent inspection findings. We will discuss appropriate corrective and preventive actions (CAPAs), equipping you with tools to help keep you in compliance and avoid common informed consent pitfalls (and ultimately avoid these findings). Attendees will be encouraged to share their experiences as we discuss methods and examine provided tools to aid in compliance through appropriate techniques for the informed consent process. 819  
**Presenter:** Janet Holwell, BA, CCRC, CCRA, TIACR, Clinical Research Consultant

**Time:** 10:50 to 11:35  
**Track:** Quality Management  
**Incorporation of Quality Data for Research Purposes**  
Special considerations may be needed when using site specific quality data in research. Institutional regulatory agencies may require full board approval where others may approve through an exemption process. Publication of data sets may also require special considerations. A review of current processes in place will be presented. 821  
**Presenter:** Estela Staggs, BSN, MCRA, CCRP, RN, CCRC, Quality Development and Metrics, Borland and Groover Clinic  

**Time:** 11:40 to 12:25  
**Track:** Quality Management  
**Dietary Supplement and Pharmaceutical Preparation: Dispensing and Accountability Can Affect the Quality of a Clinical Trial**  
Dr. Hirsh will initially review the development process with discussion of clinical trial design which will impact the study product distribution. There will be a review of the dietary supplement and pharmaceutical receipt, preparation and dispensing procedures with examples of the documentation. A review of the importance of accountability and regulatory compliance will be discussed as well as the requirements for study product retention, return, and destruction. 823  
**Presenter:** Steven Hirsh, RPh, DPM, MHSA, Director of Clinical Research, Life Extension Clinical Research Inc

**Time:** 2:00 to 3:30  
**Track:** Site Management  
**Assignment of Roles and Responsibilities**  
The roles and responsibilities of the research team will be examined. Through a series of exercises and templates, the speaker will guide coordinators, PI’s and other site staff through the study start up process with tools developed to ensure successful implementation. 827  
**Presenter:** Grace Wentzel, BA, CCRP, Director, Clinical Research Services, The Research Institute at Nationwide Children’s Hospital  
**Time:** 3:45 to 4:30  
**Track:** Site Management  
**Centralized Enrollment - Staying Audit Ready**  
There are several benefits to having a centralized enrollment office. 100% of eligibility checklists and consents submitted to our institution are reviewed for accuracy and completion upon receipt. The coordinators then enter the enrollment date into our database system which then prompts them to verify their eligibility. 100% of our eligible research participants receive a second verification within five days of enrollment. This helps the institution to be audit ready as it pertains to consents and eligibility criteria. 829  
**Presenter:** Janet Holwell, BA, CCRC, CCRA, TIACR, Clinical Research Consultant  
**Time:** 1:40 to 2:25  
**Track:** Site Management  
**Protocol Implementation Logistics**  
Ms. Albert will identify when applicable HHS and FDA regulations apply. Study logistics and the steps for protocol implementation will also be discussed as well as the required approvals needed for study start up. 825  
**Presenter:** Sara Albert, BA, MPH, Clinical Project Manager I, Leidos Biomedical Research Inc  
**Time:** 1:40 to 2:25  
**Track:** Site Management  
**Developing Effective Study Start Up Processes**  
Through a series of exercises and templates, the speaker will guide coordinators, PI’s and other site staff through the study start up process with tools developed to ensure successful implementation. 827  
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**Time:** 4:35 to 5:20  
**Track:** Site Management  
**Lean and Continuous Improvement in Clinical Research**  
Ms. Knight will introduce Lean methods and tools used in healthcare and how we used these tools to organize a continuous improvement process at our institution. Actual examples will be shared, as well as successes and challenges along the way. 831  
**Presenter:** Susan Knight, MBA, CNMT, Director, Medical Sciences Institute, BloodCenter of Wisconsin

\[\text{SOCRA 2016 Annual Conference Program}\]
Closing Plenary

Sunday, October 2, 2016

Time: 8:40 to 9:25 Track: Closing Plenary Moderator: Susanna Sellmann

**Integrative Oncology: Combining High and Low Tech Cancer Care**

Dr. Kucuk will discuss the core concepts of an important new trend in oncology care: “integrative oncology.” This is an evidence-based whole systems approach to the care of patients, which combines state of the art treatments with complementary therapies and lifestyle counseling. The goals of integrative oncology are: 1) improve outcomes, 2) improve quality of life, and 3) patient empowerment.

**Presenter:** Omer Kucuk, MD
Professor
Emory University

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Time: 9:25 to 10:10 Track: Closing Plenary

**How the Common Rule Notice of Proposed Rule Making Will Affect Clinical Research**

This presentation will provide an overview of the Common Rule Notice of Proposed Rulemaking (NPRM) published in September 2015 and explain the NPRM proposals relevant to clinical research involving human subjects. Some of the most significant NPRM proposals would mandate that US institutions engaged in cooperative research utilize a single IRB to review a study conducted at multiple sites, impose limitations on the transfer and subsequent research use of biospecimens collected in research regulated by the Common Rule, and expand the regulatory scope to apply to certain clinical trials that are not currently regulated under the Common Rule.

Ms. Odwanzy will summarize the public comment received on these proposals and address the implications of these proposals, if adopted.

**Presenter:** Laura Odwanzy, JD, MA, BA
Senior Attorney
US Department of Health and Human Services

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Time: 10:30 to 11:00 Track: Closing Plenary

**Why the “Protocol” Is the Key to a Clean Audit**

This talk will center on why following the study protocol is how you avoid a Form 483 and warning letters. Not following the protocol is one of the main problems identified by regulatory inspectors during trial audits. To start, the written protocol must be pharmacologically, ethically, and medically sound. The principal investigator, on whom full responsibility for the conduct of the study falls, signs thereby agreeing to follow this document to the letter. Any deviations are fodder for negative inspectional findings. The warning letters that will be shown are scary.

**Presenter:** Charles Pierce, MSC, MD, PhD, FCP, CPI, AAFP
President
Pierce One Consulting

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Time: 11:00 to 11:30 Track: Closing Plenary

**L-Glutamine Therapy for Sickle Cell Anemia**

Proper design and execution of a clinical trial can enhance and save the lives of many. On the other hand, poor design and execution of a clinical trial can deprive society of good products. These points will be demonstrated by reflecting on our experience in developing L-glutamine therapy for sickle cell disease.

**Presenter:** Yutaka Niihara, MD, MPH
President and CEO
Emmaus Life Sciences, Inc.

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Time: 11:30 to 12:00 Track: Closing Plenary

**Between Visits: The Use of Mobile Health Apps for Patient Self-Care and Outcomes Research**

Our mobile phones are embedded within our daily lives and are actively collecting tons of data about us, such as our physical activity levels, eating habits, and even our socializing patterns. These smart devices present a unique opportunity to deliver real-time personalized health care to individuals across the globe.

**Presenter:** Shivani Goyal, B.Eng, MASc
Project Manager
University Health Network